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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/732,408	12/09/96	REINMULLER	J HUBR1099FFFM

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QM31/0908

EXAMINER	
BLACK, J	
ART UNIT	PAPER NUMBER
3738	//
DATE MAILED:	09/08/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

<i>Office Action Summary</i>	Application No. 08/732,408	Applicant(s) Reinmuller
	Examiner ISABELLA, DAVID	Group Art Unit 3738

Responsive to communication(s) filed on Jul 20, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1, 2, and 5-42 is/are pending in the application.

Of the above, claim(s) 23-42 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1, 2, and 5-22 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Newly submitted claims 23-42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are directed to methods for using the various implants as claimed. The devices of claims 1,2,5-22 do not require implantation within the body but maybe directed to burn dressings or the like.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-42 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

2. Claims 1,2,5-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "foil" in the claims is used by the claim to mean "thin sheet," while the accepted meaning is "metallic thin sheeting."

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1,2,5,11-14,19,20,21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shane or Ledergerber (EP).

Shane discloses an implant for reconstruction of soft tissue comprising a plurality of thin pliable thin sheets having surfaces wettable by a lubricant. While Shane does not specifically disclose the thickness of the sheets, examiner contends that the sheets used by Shane fall within the broad range as claimed by applicant (ie .01mm- .2mm).

Claim 2, see covering 34 of Shane.

Claim 5, see tubes as disclosed in Ledergerber.

Claim 11, see silicone surface of Shane.

Claim 12, see lubricant of Shane.

Claims 13 and 14, see silicone and siloxane of Shane.

6. Claims 6,7,8,9,10,15,16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shane or Ledergerber as applied to claim 1 above, and further in view of Wiese.

Wiese teaches a soft tissue implant similar to that of each of Shane and Ledergerber.

Wiese teaches to use hydrogel, water swellable material inside the covering to provide for

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controlled expansion of the implant. To replace the inner structures of Shane and Ledergerber with water swellable sheets to better control the expansion of the implant would have been obvious from the teachings of Wiese.

Claim 10 polysaccharides and glucosaminoglycans are well known in the art as hydrophylic materials used in soft tissue reconstruction. The use of either of polysaccharides or glucosaminoglycans as a sheeting material would have been obvious to one with ordinary skill in the art based on engineering considerations of equivalent materials.

Claim 16 the use of cuprophane as a hydrophylic material would have been obvious to one with ordinary skill in the art based on engineering considerations of equivalent materials.

Claim 17 see Ledergerber.

7. Claim 17¹⁸ is rejected under 35 U.S.C. 103(a) as being unpatentable over Shane or Ledergerber as applied to claim 1 above, and further in view of Scarborough.

The use of an X-ray contrast or dye incorporated in to the plastic of the implant is taught by Scarborough. To incorporate an X-ray agent into the product of Shane or Ledergerber to allow the surgeon adequate means to evaluate the implant placement in vivo would have been obvious from the teachings of Scarborough.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Isabella whose telephone number is (703) 308-3060. The

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Examiner's Supervisor, Mickey Yu, may be reached at (703) 308-2672. The group receptionist may be reached at (703) 308-0858.

Should Applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 308-3590. Should Applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

John Black
John Black

GROUP 3700

jb

8/98



David J. Isabella
Primary Examiner